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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/526,329	03/15/2000	Carlo M. Croce	CR001.Np003	9316

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04/02/2003

Janet B. Smith, Thomas Jefferson University
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EXAMINER

NICKOL, GARY B

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 04/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/526,329	CROCE ET AL.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-93 is/are pending in the application.
- 4a) Of the above claim(s) 6,7,17-21,25-28 and 30-93 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8-16,22-24 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 June 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

The Amendment filed June 26, 2002 (Paper No. 9) in response to the Office Action of January 2, 2002 is acknowledged and has been entered.

Claims 1-93 are pending.

Claims 6-7, 17-21, 25-28, and 30-93 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

Claims 1-5, 8-16, 22-24, and 29 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejections Maintained:

Claims 1, 3, 9-10, 15, and 29 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons of record in Paper No. 6, page 3 and for the reasons set forth below.

The above claims are vague and indefinite for reciting the term Tc1-1b as the sole means of identifying the claimed molecule. The use of laboratory designations only to identify a particular molecule renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct molecules. The rejection can be obviated by

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amending the claims to specifically and uniquely identify Tcl-1b, for example, by SEQ ID NO.

As for Claim 29, drawn to a kit comprising a pair of primers, only one of the primers is identifiable since it is hybridizable to SEQ ID NO:38. It is not clear what the other primer recognizes and is therefore indefinite.

Claim 24 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons of record in Paper No. 6, pages 7-9.

The claim is drawn to a pharmaceutical composition comprising antisense as set forth in Claims 15 or 16. The specification lacks objective evidence or sufficient guidance to predictably enable the use of such a composition for the reasons of record. Applicants argue (Paper No. 9, page 22) that antisense nucleic acids are administered to a patient in need of therapy in order to inhibit the expression of aberrant TCL-1b. This argument has been considered but is not found persuasive as such statements do not convey to one of ordinary skill sufficient guidance that administration of the claimed pharmaceutical would predictably inhibit the expression of aberrant TCL-1b in vivo in a patient in need thereof. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

New Objections and Rejections:

Specification

The specification is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (i.e. see page 14, line 25). Applicant is requested to delete all embedded hyperlinks and/or other form of browser-executable codes. See MPEP § 608.01

The specification is further objected to under the brief description of the figures. Specifically, Figures 1-2, 5, and 9 disclose amino acid sequences without respective sequence identifiers. In the absence of a sequence identifier for each sequence, Applicant must provide a computer readable form (CRF) copy of the sequence listing, an initial or substitute paper copy of the sequence listing, as well as any amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e-f) or 1.825(b) or 1.825(d). If these sequences have been disclosed, applicant should amend the specification to include the appropriate sequence identifier.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-4, and 8-12, 22 are rejected under 35 U.S.C. 102(a) as being anticipated by Isobe *et al.* (EMBL Database, Accession No. AB018563, Submitted **October 12, 1998**, previously recited in PTO-892, Item V). See sequence comparison at the end of this action.

Isobe *et al.* teach an isolated nucleic acid encoding a polypeptide with 100% sequence similarity to SEQ ID NO: 39 from amino acid 1 to 128. This further encompasses an isolated nucleic acid encoding a fragment of a protein having an amino acid sequence of at least 10 amino acids, sharing at least 70% amino acid sequence homology to at least 25 contiguous amino acids of SEQ ID NO:39 from amino acid number 1 to 128. Isobe *et al.* further teach vectors and host cells (placental cells) expressing said vectors. Isobe *et al.* further teach that the isolated nucleic acid is 1722 base pairs which reads on an isolated nucleic acid of not more than 50 kilobases which contains a contiguous sequence of at least 18 (or 50) nucleotides encoding a Tcl-1b protein fragment or the sequence depicted in SEQ ID NO:40. Further, due to the indefiniteness of the claim language as set forth above, it is assumed for examination purposes that the nucleic acid and encoded product of the prior art is a Tcl-1b polypeptide.

Claims 13-16, 23, 29 are rejected under 35 U.S.C. 102(a) as being anticipated by Strausberg (EST Database, Accession No. AA825207 **April 21, 1998**, previously recited in PTO-892, Item W). See sequence comparison at the end of this action.

Strausberg (in Accession Number AA825207) teaches an isolated nucleic acid containing a contiguous sequence of at least 25 or at least 15 nucleotides of SEQ ID NO:38. Inherently, such a nucleic acid is capable of hybridizing under stringent conditions to a nucleotide sequence that is complementary to the cDNA sequence of SEQ ID NO:38 or that is complementary to a cDNA sequence that encodes a Tcl-1b protein which has an amino acid sequence of SEQ ID NO:39. The claims also read on primers having at least 15-25 polynucleotides in which at least one of said primers is hybridizable under stringent conditions to SEQ ID NO:38. Strausberg

further teaches a host cell that contains a recombinant vector (pT7T3D) comprising a nucleic acid capable of hybridizing under stringent conditions to a nucleotide sequence that is complementary to the cDNA sequence that encodes a Tcl-1b protein which has an amino acid sequence of SEQ ID NO:39, said nucleic acid containing a contiguous sequence of at least 25 nucleotides of SEQ ID NO:38.

Claims 1-3, 5, 8, and 13-16 are rejected under 35 U.S.C. 102(a) as being anticipated by Pekarsky *et al.* (EMBL Database, Accession No. AF110466, Submitted **December 2, 1998**). See sequence comparison at the end of this action.

Pekarsky *et al.* teach an isolated nucleic acid (Tcl-1b) with 100% sequence similarity to SEQ ID NO:38 from nucleotides 1 to 1152 which encodes a polypeptide having amino acids 1 to 128 of SEQ ID NO:39. This further encompasses an isolated nucleic acid encoding a fragment of a protein having an amino acid sequence *of at least* 10 amino acids, sharing at least 70% amino acid sequence homology to at least 25 contiguous amino acids of SEQ ID NO:39 from amino acid number 1 to 128. The reference further anticipates isolated nucleic acids capable of hybridizing under stringent conditions to a nucleotide sequence that is complementary to the cDNA sequence of SEQ ID NO:38, said nucleic acid containing a contiguous sequence of at least 25 nucleotides of SEQ ID NO:38 or antisense molecules comprising a nucleotide sequence complementary to at least fifteen nucleotides of coding sequence of a Tcl-1b mRNA which forms a stable duplex in-vivo with a Tcl-1b mRNA.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5, 8-11, 13-16, 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perkarsky *et al.* (EMBL Database, Accession No. AF110466, Submitted **December 2, 1998**).

Perkarsky *et al.* teach as set forth above (see 102a rejection)

Perkarsky *et al.* do not specifically include vectors and host cells (as claimed in Claims 9-11, and Claims 22-23)

It would have been *prima facie* obvious to anyone of ordinary skill in the art at the time the invention was made to insert the recombinant polynucleotide of Perkarsky *et al.* into vectors

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and to include host cells comprising said vectors because it is conventional in the art of molecular biology to transfer genetic information into small plasmids or vectors for the purposes of clonal propagation and to isolate and purify the encoded protein.

All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
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GBN

April 1, 2003

Carl M. Hill